No. 98-16373

IN THE

United States Court of Appeals

FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA
Plaintiff-Appellee

v.

CENTURY CLINIC, INC., a Nevada corporation;
KATRINA TANG, H.M.D., an individual
Defendants-Appellants

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEVADA

APPELLANTS' OPENING BRIEF

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permit "practice," "using the devices to test for various diseases, with the ampules, is not 'practice' (were it allowed) for a diabetes data gathering study." Id. at Tab 31, p. 27. Finally, the ALJ faulted Appellants' record-keeping, attaching no significance to the undisputed fact that Appellants, just as the other 32 study participants, were following the explicit written direction of Biosource in not maintaining LISTEN data on patients tested during the "practice" period. Id. at Tab 31, pp. 30-31. As a consequence of these findings, a penalty of $400,000.00 was assessed against Appellants.[17/] On review below, the district court, on the recommendation of a Magistrate Judge, concluded there was sufficient record evidence to sustain, as not arbitrary or capricious, the ALJ's finding. See Vol. II, Tab 40, p. 3. This appeal followed.

IV.
SUMMARY OF ARGUMENT

The finding of contempt has no support in the record and should be overturned as arbitrary and capricious agency action. To prevail, the FDA is required by law to show a violation of the subject Consent Decree by "clear and convincing evidence." The record evidence in this case does not come close to making any such showing. To the contrary, it demonstrates conclusively that Appellants at no time acted in disregard or violation of a court order, but operated throughout exactly as the Consent Decree required. They used the LISTEN System device as selected trainee-participants in an IRB-

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17/ The Consent Decree calls for a forfeiture of $200,000.00 per device upon finding it was used in violation of the Decree. Vol. I, Tab 1, p. 7, ¶ 10. The ALJ doubled the fine because Century Clinic had two devices on the premises, and the district court agreed (Vol. II, Tab 40) -- even though no evidence was introduced as to how or to what extent the second device may have been used (Vol. II, Tab 31, pp. 31, 33).

in accordance with Biosource's specific, written instructions -- just as the FDA Act (21 U.S.C. § 360j(g)) and implementing regulations (21 C.F.R. § 812.150(a)(4)) require. No grounds for contempt exist in the circumstances, and the decisions below to the contrary must be reversed as arbitrary and capricious.

VI.
CONCLUSION

For all of the foregoing reasons, the decision of the ALJ as affirmed by the court below, finding Appellants in contempt of the March 23, 1993 Consent Decree and imposing a penalty assessment of $400,000.00, must be reversed.

Dated: November 12, 1998

Respectfully submitted,

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